

**DECLARATION OF CONFORMITY**1) **Manufacturer** (*Name, department*): **Codonics, Incorporated**

Address: **17991 Englewood Drive, Middleburg Heights, Ohio 44130. USA**  
SRN: US-MF-000008190

2) **European authorized representative** for MDR and RoHS**C e p a r t n e r 4 U**

Address: **ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS;**

(on product labels printed as:

CEpartner4U , ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS [www.cepartner4u.com/](http://www.cepartner4u.com/)

SRN: **NL-AR-000000111**

3) **Product(s)** (*name, type or model/batch number, etc.*)

**Image Printers, Disc Publishers, Medication Safety Systems, and  
accessories / Film (image recording media)**

*See appendix*

4) **The product(s) described above is in conformity with:**

<u>Title</u>	<u>Document No.</u>
<b>Medical Device Regulation</b>	(EU) 2017/745
<b>Restriction of the use of certain hazardous substances (RoHS)</b>	2011/65/EU and 2015/863/EU
<b>Registration, Evaluation, and Authorization of Chemicals (REACH)</b>	1907/2006/EU
<b>ISO 13485:2016/NS-EN ISO 13485:2016</b>	245216-2017-AQ-USA-NA-PS Rev. 1.0
<b>IEC 60601-1-2:2014 4th Edition</b>	(EU) 2017/745

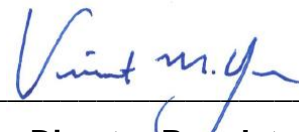
5) **Additional information** (*conformity procedure, Notified Body, CE certificate, etc.*):

Conformity assessment procedure: Medical Device Regulation: Art. 19, Annex II, III and IV

This Declaration of Conformity is issued under the sole responsibility of the manufacturer:

Middleburg Heights, Ohio

February 15, 2024



**Vincent Yee, Director Regulatory Affairs and QA**

### Appendix

Date: 2021-10-25

List of devices.

Product name	Trade name	Product code / catalogue number / unambiguous ref.	Intended purpose	Risk class / rule <sup>1</sup>	Basic UDI-DI <sup>2</sup> GMN	First date of CE-compliance
<b>MEDICAL FILM</b>	DirectVista Medical Film, Models DVB, DVC, DVBT, DVB5, sizes 8x10,11x14,14x17,14x36,14x51 ChromaVista White Film, Models DVP, CVP, sizes A, A4,11x14,14x17  Direct Vista Blue & Clear film Direct Vista Blue-5 Direct Vista Blue-T Base  Direct Vista Paper, Direct Vista White Film (A, A4,810,1114,1417) Chroma Vista Paper, Chroma Vista White Film  Chroma Vista Transparency and/or Chroma Vista Film (A, A4)  DirectVista Long Film (1436,1451)	GMDN 63183 CND Z130106  CND Z130190 (Various) CND Z13019099 (Other)	Diagnostic Procedure Hardcopy Images	I, Rule 1	See appendix UDI PAGE 081490502DVCVHCM014Y	05/14/2003 06/20/2016 11/15/2019  06/17/2004  06/17/2004  06/17/2004  02/15/2007

<sup>1</sup> See risk classification in Medical Device Regulation, annex VIII

<sup>2</sup> Product and trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device covered by the EU declaration of conformity, such as a photograph, where appropriate, as well as its intended purpose. Except for the product or trade name, the information allowing identification and traceability is provided by the Basic UDI-DI



<b>IMAGERS</b>	<p>Horizon Medical Multimedia Dry Imagers</p> <p><b>Ci</b> Large Format Color, Gray Scale, Film</p> <p><b>GS</b> Large Format Gray Scale</p> <p><b>SF</b> Small Format Color, Gray Scale, Film</p> <p><b>G</b> (1417) Three Input Single Media</p> <p><b>G1</b> Single Input Multi Format, Gray Scale, Film</p> <p><b>G2</b> Dual Input Multi Format, Gray Scale, Film</p> <p><b>XL</b> Medical Long Film Imager (1436 &amp; 1451)</p>	GMDN 36782/ CND Z110706	Diagnostic Procedure Image Printing	I, Rule 1 & 13	See appendix UDI PAGE 081490502HZMMI01G9	03/13/2002
<b>Medication Management</b>	Safe Label System SLS 500i/550i/600iPoint of Care Station (PCS)	GMDN 37588 CND A0704	Medication Preparation and Label Printing	I, Rule 1 & 13	See appendix UDI PAGE 081490502SLSPCS01XR	03/03/2011
<b>Medical Disc Recorders</b>	Virtua Medical Image Disc Publisher, Models Virtua, Virtua XR, Virtus E, Virtua C	GMDN 64454 CND Z11069099	Diagnostic Image Disc Recording and Label Printing	I, Rule 1 & 13	See appendix UDI PAGE 081490502VRMDP01KK	06/27/2006  07/11/2007





<b>Codonics DirectVista Thermal Film, 1114-DVB</b>	<b>1114-DVB Blue Base Film (500 sheets/5 cassette case)</b>	<b>10814905020622</b>
Codonics DirectVista Thermal Film, 810-DVB	810-DVB Blue Base Film (100 sheet cassette)	00814905020632
<b>Codonics DirectVista Thermal Film, 810-DVB</b>	<b>810-DVB Blue Base Film (500 sheets/5 cassette case)</b>	<b>10814905020639</b>
Codonics DirectVista Thermal Film, 810-DVC	810-DVC Clear Base Film (100 sheet cassette)	00814905020649
<b>Codonics DirectVista Thermal Film, 810-DVC</b>	<b>810-DVC Clear Base Film (500 sheets/5 cassette case)</b>	<b>10814905020646</b>
Codonics DirectVista Thermal Film, 810-DVB	810-DVB Blue Base Film (100 sheet boxed)	00814905021042
<b>Codonics DirectVista Thermal Film, 810-DVB</b>	<b>810-DVB Blue Base Film (500 sheets/5 boxes case)</b>	<b>10814905021049</b>
Codonics DirectVista Thermal Film, 810-DVC	810-DVC Clear Base Film (100 sheet box)	00814905021059
<b>Codonics DirectVista Thermal Film, 810-DVC</b>	<b>810-DVC Clear Base Film (500 sheets/5 boxed case)</b>	<b>10814905021056</b>
Codonics DirectVista Thermal Film, 1436-DVB	1436-DVB Blue Base Film (25 sheet cassette)	00814905020656
Codonics DirectVista Thermal Film, 1451-DVB	1451-DVB Blue Base Film (25 sheet cassette)	00814905020663
<b>Codonics DirectVista Thermal Film, 1436-DVB</b>	<b>1436-DVB Blue Base Film (100 sheets/4 cassette case)</b>	<b>10814905020653</b>
<b>Codonics DirectVista Thermal Film, 1451-DVB</b>	<b>1451-DVB Blue Base Film (100 sheets/4 cassette case)</b>	<b>10814905020660</b>
Codonics DirectVista Thermal Film, 1417-DVBT	1417-DVBT Blue Base Film (100 sheet cassette)	00814905020670
<b>Codonics DirectVista Thermal Film, 1417-DVBT</b>	<b>1417-DVBT Blue Base Film (500 sheets/5 cassette case)</b>	<b>10814905020677</b>
Codonics DirectVista Thermal Film, 810-DVBT	810-DVBT Blue Base Film (100 sheet cassette)	00814905020687
<b>Codonics DirectVista Thermal Film, 810-DVBT</b>	<b>810-DVBT Blue Base Film (500 sheets/5 cassette case)</b>	<b>10814905020684</b>
Codonics DirectVista Paper/White Film, A-DVP	A-DVP White Base Film, (80 sheet cassette)	00814905020694
<b>Codonics DirectVista Paper/White Film, A-DVP</b>	<b>A-DVP White Base Film, (400 sheets/5 cassette case)</b>	<b>10814905020691</b>



Codonics DirectVista Paper/White Film, A4-DVP	A4-DVP White Base Film, (80 sheet cassette)	00814905020700
<b>Codonics DirectVista Paper/White Film, A4-DVP</b>	<b>A4-DVP White Base Film, (400 sheets/5 cassette case)</b>	<b>10814905020707</b>
Codonics DirectVista Paper/White Film, 1417-DVP	1417-DVP White Base Film, (80 sheet cassette)	00814905020717
<b>Codonics DirectVista Paper/White Film, 1417-DVP</b>	<b>1417-DVP White Base Film, (400 sheets/5 cassette case)</b>	<b>10814905020714</b>
Codonics DirectVista Paper/White Film, 1114-DVP	1114-DVP White Base Film, (80 sheet cassette)	00814905020724
<b>Codonics DirectVista Paper/White Film, 1114-DVP</b>	<b>1114-DVP White Base Film, (400 sheets/5 cassette case)</b>	<b>10814905020721</b>
Codonics ChromaVista Paper/WhiteFilm, A-CVP	A-CVP White Base Film, (50 sheet cassette)	00814905020731
<b>Codonics ChromaVista Paper/WhiteFilm, A-CVP</b>	<b>A-CVP White Base Film, (100 sheets/2 cassette case)</b>	<b>10814905020738</b>
Codonics ChromaVista Paper/WhiteFilm, A4-CVP	A4-CVP White Base Film, (50 sheet cassette)	00814905020748
<b>Codonics ChromaVista Paper/WhiteFilm, A4-CVP</b>	<b>A4-CVP White Base Film, (100 sheets/2 cassette case)</b>	<b>10814905020745</b>
Codonics DirectVista Thermal Film, 1417-DVB5	1417-DVB5 Blue Base Film (100 sheet box)	00814905020885
<b>Codonics DirectVista Thermal Film, 1417-DVB5</b>	<b>1417-DVB5 Blue Base Film (500 sheets/5 box case)</b>	<b>10814905020882</b>
Codonics DirectVista Thermal Film, 1114-DVB5	1114-DVB5 Blue Base Film (100 sheet box)	00814905020892
<b>Codonics DirectVista Thermal Film, 1114-DVB5</b>	<b>1114-DVB5 Blue Base Film (500 sheets/5 box case)</b>	<b>10814905020899</b>
Codonics DirectVista Thermal Film, 810-DVB5	810-DVB5 Blue Base Film (100 sheet box)	00814905020908
<b>Codonics DirectVista Thermal Film, 810-DVB5</b>	<b>810-DVB5 Blue Base Film (500 sheets/5 box case)</b>	<b>10814905020905</b>
Codonics DirectVista Thermal Film, 1417-DVB5	1417-DVB5 Blue Base Film (100 sheet cassette)	00814905020915
<b>Codonics DirectVista Thermal Film, 1417-DVB5</b>	<b>1417-DVB5 Blue Base Film (500 sheets/5 cassette case)</b>	<b>10814905020912</b>
Codonics DirectVista Thermal Film, 1114-DVB5	1114-DVB5 Blue Base Film (100 sheet cassette)	00814905020922



<b>Codonics DirectVista Thermal Film, 1114-DVB5</b>	<b>1114-DVB5 Blue Base Film (500 sheets/5 cassette case)</b>	<b>10814905020929</b>
Codonics DirectVista Thermal Film, 810-DVB5	810-DVB5 Blue Base Film (100 sheet cassette)	00814905020939
<b>Codonics DirectVista Thermal Film, 810-DVB5</b>	<b>810-DVB5 Blue Base Film (500 sheets/5 cassette case)</b>	<b>10814905020936</b>
Codonics DirectVista Thermal Film, 1436-DVB5	1436-DVB5 Blue Base Film (25 sheet cassette)	00814905020946
<b>Codonics DirectVista Thermal Film, 1436-DVB5</b>	<b>1436-DVB5 Blue Base Film (100 sheets/4 cassette case)</b>	<b>10814905020943</b>
Codonics DirectVista Thermal Film, 1451-DVB5	1451-DVB5 Blue Base Film (25 sheet cassette)	00814905020953
<b>Codonics DirectVista Thermal Film, 1451-DVB5</b>	<b>1451-DVB5 Blue Base Film (100 sheets/4 cassette case)</b>	<b>10814905020950</b>
<b><u>DISC PUBLISHERS</u></b> <b><u>BASE MODEL</u></b> <b><u>VRMDP01</u></b>	<b><u>Virtua Medical Disc Publisher</u></b>	<b><u>081490502VRMDP01KK</u></b>
Codonics Virtua® Medical Disc Publisher	Integrated Virtua DICOM Server & Medical Disc (CD/DVD) Publisher System	00814905020328
Codonics Virtua® XR Medical Disc Publisher	Integrated Virtua XR DICOM Server & Medical Disc (CD/DVD) Publisher System	00814905020335
Codonics Virtua® C and E Medical Disc Publisher	Integrated Virtua C DICOM Server & Medical Disc (CD/DVD) Publisher System	00814905020359
<b><u>MEDICATION LABEL SYSTEM</u></b> <b><u>BASE MODEL</u></b> <b><u>SLSPCS01</u></b>	<b><u>SAFE LABEL SYSTEM POINT of CARE SYSTEM</u></b>	<b><u>081490502SLSPCS01XR</u></b>
Codonics Safe Label System®(SLS) 500i Point of Care Station	Integrated computer-based barcode scan & print system automatically to verify drugs & print labels of prepared drugs & other items	00814905020229
Codonics Safe Label System®(SLS) 550i Point of Care Station	Integrated computer-based barcode scan & print system automatically to verify drugs & print labels of prepared drugs & other items	00814905020366



<b>Codonics Safe Label System®(SLS) 600i Point of Care Station</b>	<b>Integrated computer-based barcode scan &amp; print system automatically to verify drugs &amp; print labels of prepared drugs &amp; other items</b>	<b>00814905021103</b>
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**Product ALIAS CROSS REFERENCE**

Note:

\* SRM Products are Horizon imagers and media manufactured by Codonics and Labelled /Packaged for SRM Romania

\* GE Healthcare and OEC Products are Horizon imagers and media manufactured by Codonics and Labelled /Packaged for GE Healthcare

DEVICE NAME	MODEL	RISKCLASS / RULE	First Date of CE Marking
SRM Medical imager G2 part HRG2T-SRM-01 SRM Medical imager Gs part HRGsT-SRM-02 CNFG 8.xx or higher	SRM Imager	I, Rule 1 & 13 (Image printer)	06/17/2019 (MDD)
SRM media of Various sizes of DVC/DVB/DVBT/DVB5 (Radiographic Film)	SRM 8"x10", 11"x14", 14"x17" Medical Imaging Film	I, Rule 1 (Hardcopy Media)	06/17/2019 (MDD)

IMAGERS ALIAS CROSS REFERENCE	Codonics Horizon Ci	Codonics Horizon G2	Codonics Horizon GS	Codonics Horizon G (1417/810)	Codonics Horizon SF	Codonics Horizon XL LONG FILM
Imagers/Media	GE Multi-media IMAGER Ci	SRM Medical imager G2	SRM Medical imager GS GE Multi-media Imager GS		GE Multi-media & OEC Imager SF	GE Multi-media Imager XL
DirectVista Film Blue 1417-DVB		SRM Medical Imaging Film	SRM Medical Imaging Film			





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		SRM Medical Imaging Film		
<b>Blue 1114-DVB</b>	GE Medical Imaging Film DVB	SRM Medical Imaging Film	GE Medical Imaging Film DVB	
<b>Blue 810-DVB</b>	SRM Medical Imaging Film GE Medical Imaging Film DVB	SRM Medical Imaging Film	SRM Medical Imaging Film GE Medical Imaging Film DVB	GE Medical Imaging Film DVB
Codonics DirectVista Thermal Film, 810- DVB				OEC Boxed Film 810-DVB Blue Base Film (100 sheet boxed)
<b>Codonics DirectVista Thermal Film, 810- DVB</b>				<b>810-DVB Blue Base Film (500 sheets/5 boxes case)</b>
Codonics DirectVista Thermal Film, 810- DVC				810-DVC Clear Base Film (100 sheet box)
<b>Codonics DirectVista Thermal Film, 810- DVC</b>				<b>810-DVC Clear Base Film (500 sheets/5 boxed case)</b>
<b>Blue 1436-DVB</b>				GE Medical Imaging Film DVB
<b>Blue 1451-DVB</b>				GE Medical Imaging Film DVB
<b>White Film</b>				
<b>1417-DVP</b>	GE Medical Imaging Grayscale Paper DVP		GE Medical Imaging Grayscale Paper DVP	GE Medical Imaging Grayscale Paper DVP
<b>White Film</b>				
<b>A4-DVP</b>	GE Medical Imaging Grayscale Paper DVP		GE Medical Imaging Grayscale Paper DVP	GE Medical Imaging Grayscale Paper DVP